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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,248	10/16/2001	Mark A. Hoffman	CRNC.83071	6008

7590 07/14/2004

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EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,248	HOFFMAN ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-30,55-60 and 85-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-30,55-60 and 85-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 October 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/15/02, 4/4/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Applicant's election of Group III, claims 25-30, 55-60, and 85-90 in the reply filed on 4/22/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

An action on the merits of the elected claims follows.

Information Disclosure Statement

The IDS's filed 5/15/02 and 4/4/03 have been fully considered.

Drawings

Figure 5 is objected to because elements of the Figure are obscured and/or difficult to see due to dark shading in the Figure. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled

"Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. **The objection to the drawings will not be held in abeyance**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25-26, 29-30, 55-56, 59-60, 85-86 and 89-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over ICHIKAWA (Internal Medicine (July, 2000) vol. 39, no. 7, pp. 523-524) in view of EVANS et al. (IDS ref: Science (Oct. 1999) vol.

286, pp. 487-491) and SUNDBERG et al. (IDS ref: J. Clin. Pharm. (2000) vol. 40, pp. 930-938)

Claims 25, 55, and 85 are directed to a method for processing hereditary data, and to a computer system and medium for performing the method wherein the method comprises receiving a genetic test result value for a person, determining if the test result value comprises polymorphic data associated with an atypical clinical event, accessing a list of risk-associated agents, and outputting an "interpretation" of the genetic test result value and the list of risk-associated agents. Claims 26, 56, and 86 limit the method to comprise determining if a patient has been exposed to a risk-associated agent. Claims 29-30, 59-60 and 89-90 limit the method to comprise initiating a clinical action if a patient has been exposed to a risk-associated agent, specifically to inform a clinician to no longer administer the agent.

ICHIKAWA teaches a method for processing hereditary (genetic) data related to response to azathriopine or mercaptopurine (clinical agents) wherein genetic tests results for individual patients are received, the presence of a polymorphism is determined, wherein particular mutations or polymorphisms are associated with atypical clinical events (side effects) of administration of various drugs, and a decision made to change a drug dosage (p. 523). Since drug dosages are based on the genetic testing results in the method of ICHIKAWA, the method necessarily includes a step of outputting the test results and the list of drugs. ICHIKAWA also teaches that one decision based on the results may be discontinuation of drug use (p. 523, left column). As patient response to drugs is known in the method of ICHIKAWA, the method of

ICHIKAWA also necessarily includes a step of accessing the patient's medical record. ICHIKAWA does not specifically teach electronic medical records, a computer-implemented method, a computer system or a computer-readable medium.

EVANS teaches association of a variety of drugs with polymorphisms, which are also known to be associated with "idiosyncratic" drug reactions or altered drug sensitivity (p. 489, Table 1). It is noted that Table 1 of EVANS includes the drugs and at least one of the polymorphic sites taught by ICHIKAWA. EVANS further teaches automated systems to associate an individual's genotype with polymorphic genes in order to optimize drug administration and disease treatment (p. 490, right column).

It would have been obvious to one of ordinary skill in the art at the time of invention to have computerized, or automated, the genetic screening method of ICHIKAWA, as taught by EVANS, where the motivation would have been to facilitate use of the method and to optimize drug administration, as taught by both EVANS and SUNDBERG.

Claims 27-28, 57-58, and 87-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over ICHIKAWA (Internal Medicine (July, 2000) vol. 39, no. 7, pp. 523-524) in view of EVANS et al. (IDS ref: Science (Oct. 1999) vol. 286, pp. 487-491) as applied to claims 25-26, 29-30, 55-56, 59-60, 85-86 and 89-90 above, and further in view of SUNDBERG et al. (IDS ref: J. Clin. Pharm. (2000) vol. 40, pp. 930-938) and FEY et al. (US Pub. 20020038227, filed 2/26/01).

The claims recite a method, computer system and medium for processing hereditary data, as set forth above. Claims 27-28, 57-58, and 87-88 limit the method to further comprise accessing an electronic medical record, specifically in a comprehensive healthcare system.

ICHIKAWA and EVANS make obvious a computerized method for processing hereditary data, as set forth above. ICHIKAWA's method necessarily includes a step of accessing the patient's medical record, also as set forth above. Neither ICHIKAWA nor EVANS specifically teaches electronic medical records.

SUNDBERG teaches that drug industries regularly genotype patients and suggests inclusion of genotypes in a patient's medical record in order to individualize drug treatment (p. 936).

FEY teaches an electronic database for comprehensive/centralized health care management wherein the database comprise a plurality of clinical information and test results for individuals (paragraphs, 4, 43 and 49).

It would have been obvious to have accessed electronic medical records, as suggested by the access to genotypes in patient medical records and clinical trial genotyping of SUNDBERG, in the method of ICHIKAWA and EVANS, where the motivation would have been to individualize drug treatment regimens, as taught by all of ICHIKAWA, EVANS, and SUNDBERG. It would further have been obvious to have included, and therefore accessed, genetic testing results in a comprehensive healthcare system/database, as taught by FEY, in the method of ICHIKAWA, EVANS, and SUNDBERG, where the motivation would have been to perform accurate risk

assessment and to optimize individual treatment regimens, as taught by all of ICHIKAWA, EVANS, and FEY (paragraphs 8 and 95).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
7/12/04